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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,653	04/20/2004	C. Randal Mills	15672US01	4918

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EXAMINER	
YOO, REGINA M	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,653	MILLS ET AL.	
	Examiner	Art Unit	
	Regina Yoo	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-74* is/are pending in the application.

4a) Of the above claim(s) *14-26 and 43-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13, 27-42 and 63-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

Response to Amendment

The amendment filed on 7/25/2007 has been received and claims 1-11 and 13-74 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-13, in the reply filed on 7/25/07 is acknowledged. The traversal is on the ground(s) that "the search and examination for those claims would not constitute an undue burden". This is not found persuasive because a separate search and examination is required for examining different aspects of the non-elected groups that are not required by the elected group.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-26 and 43-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/25/07.

3. Claims 27-42 and 63-64 directed to of Group III, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104 as the current amended claims now include the step of applying tension to an implant during one or more of the steps recited.

4. This application contains claims 14-26 and 43-62 drawn to an invention nonelected with traverse in the reply filed on 7/25/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-11, 13, 27, 31-42 and 63-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Cook (6206931).

As to Claims 1, 13, 27, 31-39 and 63-64, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant at least partially comprises a soft tissue (page 12, line 23), the process comprising:

(a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols (page 18, Table I Step 2 with fluid E; wherein during Step 2, alcohol is perfused into the implant – see p.18 line 20 to p.19 line 1);

(b) contacting the implant with an oxidizing sterilant (page 18, Table I Step 3 with fluid C which is hydrogen peroxide, that functions as a disinfectant and a decontaminating agent, for about 1 minute, which is less than about 80 minutes; wherein during Step 3, peroxide is perfused into the implant – see p.19 lined 2-4); and

(c) contacting the implant with a rinsing fluid (page 18, Table I Step 4; page 19, lines 9-12 with fluid such as B, which is a detergent, and/or fluid E, which is an alcohol).

Mills ('037) does not appear to specifically teach that the method is further comprised of applying tension or kinematic restraint to the soft tissue at least during part of step (b) or during each of steps (a), (b) and (c).

Cook ('931) discloses that a tissue source for an implant is sterilized to yield a collagen-based matrix (Abstract) that can be "employed to prepare tissue graft constructs useful in orthopedic soft tissue applications, for example in tendon or ligament repair" (Col. 11, lines 54-56) and further discloses that "for tendon and ligament replacement applications, ...[the implant tissue] can be conditioned by the prolonged application of a load on the longitudinal axis of the segment (e.g. by suspending a weight from the segment) ... [or] can be preconditioned by stretching in the lateral dimension" (Col. 11, lines 62-67 and Col. 12, lines 1-3).

While Cook ('931) appears to disclose that the tensioning step occurs after the disinfection steps, it would have been obvious to one of ordinary skill in this art at the time of invention to provide the tensioning step during one or all the steps of the disinfection process of a soft tissue such as a tendon or a ligament in the method of Mills in order to obtain a properly conditioned/tensioned connective tissue graft to implant in a patient, since it was well known in the art at the time of invention to tension a graft before the actual implantation in order to (1) decrease its elongation once implanted and (2) tensioning of the graft after the graft is partially in place is awkward to perform. Furthermore, tensioning of the implanted tissue prior to implantation also (3)

allows a full range of motion for a patient after receiving the implant which is the reason why the "grafts used in orthopedic applications are typically placed under tension in their surgical installation" ('931, Col. 12, lines 43-44).

As to Claims 2 and 65, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12).

As to Claims 3 and 66, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising:

d) contacting the implant with an oxidizing sterilant (page 19, lines 20-24; Table II); and

(e) contacting the implant with a rinsing fluid (page 20, Table II Step 4', or page 21, lines 1-3).

As to Claims 4, 40 and 67, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the contact with the implant (page 18, Table I Step 4 and page 19, lines 4-7 and 10-12, or page 20, Table II Step 4' and page 21, lines 1-3).

As to Claims 5 and 68, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c) (page 18, Table I Step 4).

As to Claims 6 and 69, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein prior to step (b) (for example during step (a)) alcohol is contacted with the implant (page 18, Table I Step 2 with fluid E). While Mills ('037) does not specifically teach that the implant contains an amount of the alcohol in the implant, it would have been obvious to one of ordinary skill in this art that the alcohol remains in the implant after the treatment as Mills does not disclose that the alcohol is removed to waste before carrying out step (b); only fluid removal step mentioned by Mills is "after step 4 in Table I, the cleaning fluid is removed to waste under positive pressure" (page 19, line 9).

As to Claims 7 and 70, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid is selected from the group consisting of alcohols, acetone, water, and mixtures thereof (page 18, Table I Step 4 with fluid E or mixtures; page 20, Table II Step 4' with fluid J or mixtures; page 19, lines 10-11; page 21, lines 1-2).

As to Claims 8 and 71, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms (page 18, Table I Step 4 with fluid E where the alcohol is "ethanol or isopropanol" or page 20, Table II Step 4' where the fluid is J – in the form of "isopropanol,.methanol").

As to Claims 9 and 72, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein step (b) comprises contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10% (page 18, Table I Step 3 with fluid C where the concentration is 3% or page 20, Table II with fluid I where the concentration is 6%).

As to Claims 10, 41 and 73, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises at least one tendon or ligament (page 32, line 5).

As to Claims 11, 42 and 74, Mills ('037) discloses a process for making an implant more suitable for implantation into a recipient (Abstract), wherein the implant comprises a tendon having bone attached thereto (page 31, lines 21-31).

Thus, Claims 1-11, 13, 27, 31-42 and 63-74 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037) and Cook ('931).

7. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills (WO 00/29037) in view of Cook (6206931) as applied to claim 27 above, and further in view of Grood and Noyes (JB & JS, 58: 1083-1088,1976).

Mills ('037) and Cook ('931) are relied upon for disclosure described in the rejection of claim 27 under 35 U.S.C. 103(a).

While Cook ('931) discloses that a load is applied to implant by suspending a weight from the implant for a period of time to allow about 10-20% elongation of the implant, Cook ('931) does not appear to specifically teach that the load is from about 0.5 Newton to about 20 Newtons, or from about 1 to about 10 Newtons, or from about 3 Newtons to about 5 Newtons of tension.

Grood and Noyes discloses that an implant is subjected to tension in the ranges of 0.5 Newton to about 20 Newtons, or from about 1 to about 10 Newtons, or from about 3 Newtons to about 5 Newtons in order to ensure that the implant has necessary mechanical properties to function properly when implanted (see entire document, particularly Figures 2 and 5).

It was known in the art at the time of invention to tension a soft tissue implant to various loads and it would have been obvious to one of ordinary skill in this art at the time of invention to provide tension in the range from about 0.5 Newton to about 20

Newtons, or from about 1 to about 10 Newtons, or from about 3 Newtons to about 5 Newtons in the process of Mills as modified by Cook in order to ensure that the implant is adequately preconditioned to handle the actual loading conditions when implanted as shown by Grood and Noyes.

Thus, Claims 28-30 would have been obvious within the meaning of 35 U.S.C. 103(a) over the combined teachings of Mills ('037), Cook ('931) and Grood and Noyes.

Response to Arguments

8. Applicant's arguments filed 7/25/07 have been fully considered but they are not persuasive.

In particularly, Applicant's argument regarding rejection of claim 6 on page 14, lines 1-10 of Remarks is not found persuasive. Applicant points out that the " "deep tissue interpenetration by cleaning solution is achieved by oscillating the pressure in the chamber while adding and removing various cleaning solutions" (p.17, lines 14-15)" and this indicates "that the cleaning solutions in each steps 1, 2, 3 and 4 in Table I can be added and removed." However, the reference that Applicant quotes specifically points out that this process involves "oscillating the pressure in the chamber" for the removal of the cleaning solution and it is seen in Table I, step 2 pointed out in the previous Office Action does not involve oscillation of pressure (only step 4 does) and thus does not remove the alcohol from the implant. It is noted that the claim does not exclude removal of alcohol; it merely requires that prior to step b, the implant contains an amount of alcohol in the soft tissue sufficient to reduce damage from oxidation to the soft tissue.

As to Applicant's arguments regarding claims 1 and 12-13, it was well known in the art to disinfect implants as demonstrated by Mills ('037) and Cook ('931) as well as to tension implants as demonstrated by Cook ('931). While Cook ('931) does not appear to specifically teach application of tension during the period when the implant is in contact with the oxidizing agent or other agents, it would have been obvious to one of ordinary skill in this art at the time of invention to combining both steps into one step in order to optimize the processing method by shortening/decreasing the processing time through processing the implant in a parallel fashion rather than in a serial fashion so as to obtain a properly conditioned/tensioned implant as stated above in a reduced period of time. It would have been obvious to one of ordinary skill in this art at the time of invention that there is a reasonable expectation of success, with only the expected results attained. In addition, there is no teaching in the art that suggests to require the steps to be performed separately.

As to applicant's assertion that that there is an unexpected benefit of tensioning while a peroxide is applied, Examiner assessed the result in Table 1 of the Specification and deems that at the upper limit of the result for peroxide and detergent contacting the implant while loaded is 18.451 and the lower limit of the result for peroxide and detergent contacting the implant without tension is 19.104, the level of denatured collagen is not statistically significant to justify that tensioning is beneficial, particularly in view of relatively large standard deviation values. Moreover, Applicant's assertion that

peroxide + tension has unexpected result, as stated in the Specification portion pointed out by the Applicant in the Remarks, is not specifically supported by the Table 1 since the load test results were obtained when both peroxide and detergent were used on the implant.

As to Applicant's argument that "none of [the] reasons [provided] would lead a person of ordinary skill to include a tensioning step during a disinfection process rather than separately from such a process", Examiner would disagree and point out that in the previous Office Action in p. 12 lines 13-16 Examiner has indicated that tensioning is provided before/during/after the disinfection process in order to obtain a properly conditioned/tensioned implant end product.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references relate either to the field of the invention or subject matter of the invention, but are not relied upon in the rejection of record: 6572650.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina Yoo whose telephone number is 571-272-6690. The examiner can normally be reached on Monday-Friday, 9:30 am - 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RY

GLADYS P CORCORAN
SUPERVISORY PATENT EXAMINER